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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/438,600	11/12/99	SHIEH	C 99.723

HM12/0615
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EXAMINER	
PHAM, M	
ART UNIT	**PAPER NUMBER**
1641	5

DATE MAILED: 06/15/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/438,600	Applicant(s) SHIEH ET AL.	
	Examiner Minh-Quan K. Pham	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on *17 May 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-15, in Paper No. 4 is acknowledged. The traversal is on the ground(s) that there is no undue burden on the examiner to examine the method claims and the apparatus claims at the same time. This is not found persuasive because the additional search required for the method claims would have placed undue burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 7, the phrase "including" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 7, the word "means" is preceded by the word(s) "patterned by" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claim 9 recites an improper Markush group. To obviate this rejection, the phrase "members from a group consisting of" should be amended to read "members are selected from a group consisting of".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102((e), f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 8-9, 12, and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Machida et al. (US 5,759,866).

Machida et al. disclose a assay device comprising a channel formed in a substrate, such as polystyrol resin, acryl resin, etc. (see column 2, lines lines 42-56; and column 4, lines 50-58). The channel has a sample treating zone containing a porous material having immobilized thereto a member of a specific binding pair, e.g. antibody. (see column 6, lines 43-46). The porous material may be a nitrocellulose filter, cellulose acetate filter, nylon membrane, filter paper and glass filter (see column 4, lines 38-41). The device is associated with an optical detector to measure the binding reaction at the porous material (see column 8, lines 58-61).

Machida et al., however, differ from the claimed invention because they do not disclose multiple sample treating zones.

It would have been obvious for one of ordinary skill in the art to fabricate more than one sample treating zones in the device of Machida et al. in order to serially perform multiple binding steps in an assay. For example, by using more than one sample treating zones in the apparatus of Machida et al., it is possible to capture multiple analytes in a single flow through, which would have the advantage of increasing the speed of analysis. Further, by using more than one sample treating zones in the apparatus of Machida et al., it is possible to have a zone for binding of interferents, such as cell debris, proteins, or DNA, and a zone for binding of the

analyte. Thus, by the removing the interferents before binding of the analyte, it is possible to increase the sensitivity and accuracy of the binding assay.

Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Machida et al. (US 5,759,866) as applied to claims 1-3, 8-9, 12, and 14-15 above, and further in view of Hancock et al. (US 5,716,825).

See above for the disclosure of Machida et al.

Machida et al., however, differ from the claimed invention, because they do not disclose that the specific binding pair member is DNA.

Hancock et al. disclose the use of a microfluidic apparatus for the analysis of DNA wherein DNA are immobilized in the microchannel.

Therefore, it would have been obvious to one of ordinary skill in the art to immobilized DNA as a specific binding pair member, as taught by Hancock et al., in the modified device of Machida et al., because the immobilized DNA can be used in PCR or hybridization analysis, which are essential in the diagnosis and management of human disease (see Hancock et al.: column 1, lines 16-30).

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Machida et al. (US 5,759,866) as applied to claims 1-3, 8-9, 12, and 14-15 above, and further in view of Lofas et al. (1990), *Chemical Communications*, pp. 1526-1528.

See above for the disclosure of Machida et al.

Machida et al., however, differ from the claimed invention, because they do not disclose the immobilization of binding members in a hydrogel.

Lofas et al. disclose the immobilization of ligands (specific binding members) in a hydrogel for purposes of biospecific interaction analysis (see Abstract; and Figure 1).

Therefore, it would have been obvious to one of ordinary skill in the art to use hydrogels immobilize specific binding members, as taught by Lofas et al., in the modified device of Machida et al., because the hydrogel has the advantage of increased immobilization capacity (see Lofas et al.: Abstract).

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Machida et al. (US 5,759,866) as applied to claims 1-3, 8-9, and 12 above, and further in view of Zanzucchi et al. (US 5,585,069).

See above for the disclosure of Machida et al.

Machida et al., however, differ from the claimed invention, because they do not disclose that the fluid is propelled using electrically.

Zanzucchi et al. disclose a microfluidic device wherein the fluid movement is accomplished through electrokinetic pumps (see column 7, lines 33-39).

Therefore, it would have been obvious to one of ordinary skill in the art to pump fluids through the modified device of Machida et al. using electrokinetic pumping, as taught be Zanzucchi et al., because electrokinetic pumps have the advantage of containing no moving parts, thus requiring very little maintenance.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Wilding et al (US 5,304,487); and Parce et al. (US 5,942,443) are cited to show microfluidic apparatuses used in binding assays.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Quan K. Pham whose telephone number is (703) 305-1444. The examiner can normally be reached on Monday to Friday, 8 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Minh-Quan K. Pham, Ph.D.
June 8, 2000

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641